

Attorney's File Number: P02975

**COMBINED DECLARATION AND POWER OF ATTORNEY**

As a below-named inventor, I hereby declare that:

**TYPE OF DECLARATION**

This declaration is of the following type:

- ☒ original  
☐ design  
☐ divisional  
☐ continuation  
☐ continuation-in-part (CIP)

**INVENTORSHIP IDENTIFICATION**

My residence, post office address and citizenship are as stated below next to my name. I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

**IMPROVED PROCESS FOR THE PRODUCTION  
OF SUSTAINED RELEASE DRUG DELIVERY DEVICES**

the specification of which is attached hereto.

**ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR**

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

**PRIORITY CLAIM (35 U.S.C. §119)**

I hereby claim foreign priority benefits under Title 35, United States Code, §119 of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

  X   no such applications have been filed.  
      such applications have been filed as follows:

**PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS  
 (6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION  
 AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. §119**

Country	Application Number	Date of Filing (day, month, year)

**CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S)  
UNDER 35 U.S.C. §120**

I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) that is/are listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in that/those prior application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application(s) and the national filing date of this application.

US Applications	US Filing Date	Status (check one)	
		Patented	Pending

I hereby claim the benefit under Title 35, United States Code §119(e) of any United States provisional application(s) listed below.

<u>US Application</u>	<u>US Filing Date</u>
1. 60/264,441	January 26, 2001
2.	

### POWER OF ATTORNEY

As a named inventor, I hereby appoint the following attorney(s) and/or agent(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith:

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**DECLARATION**

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application of any patent issued thereon.

**SIGNATURE(S)**

Full name of first joint inventor, if any: Michael J. Brubaker

Inventor's signature: \_\_\_\_\_

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Full name of second joint inventor, if any: Pavlos Papadopoulos

Inventor's signature: \_\_\_\_\_

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Full name of third joint inventor, if any: Ramesh Krishnamoorthy

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applied to achieve uninterrupted and uniform coatings, which adds significant bulk to the device. Thus, the devices tend to be larger than necessary as a result of the thickness needed to seal the ends of the inner core and seal it to the suture tab. In addition to adding bulk, multiple layer devices are more difficult to manufacture reproducibly and are more difficult to produce by commercial manufacturing procedures. Also, the various layers can be made of materials that are relatively incompatible with one another adding to the difficulties in coating. Often devices such as these require a plurality of manual assembly steps that is time consuming, limits available supply, and adds variability.

U.S. Patent No. 5,902,598 also presents solutions to some of the problems associated with manufacturing small devices. The device in U.S. Patent No. 5,902,598 includes a third permeable coating layer that essentially completely covers the device. While the third coating layer improves the structural integrity of the device and helps to prevent potential leakage, some manufacturing difficulties can limit scaled up manufacturing. For example, consistent application of the outermost coating layer and reproducibility in manufacturing can be problems with designs which require manual assembly, a significant number of steps in the assembly process, or outer dip coatings.

The problem of device size is extremely important in the design of devices for implantation into the limited anatomical spaces such as small organs like the eye. Larger devices require more complex surgery to both implant and remove. The increased complexity can result in complication, longer healing or recovery periods, and potential side effects (e.g. increased chance of astigmatism). Further, the extra polymer required to achieve a uniform coating reduces the potential internal volume of the implant and hence limits the amount of drug that can be delivered, potentially limiting both efficacy and duration.

Also, failure of some of these devices in use can lead to a dumping of the agent, which can cause harm to the mammalian organism being treated.

It would, therefore, be desirable to have a structurally stable device that can be reproducibly manufactured and manufactured by commercial techniques. As a result of

all of the above, there remains a long felt need in the art for an improved device and an improved process of producing such a device for providing sustained release of a drug to a mammalian organism to obtain a desired local or systemic physiological or pharmacological effect, especially for ocular use.

### SUMMARY OF THE INVENTION

The sustained release drug delivery device according to the present invention comprises:

- a) a drug core comprising at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect;
- b) an impermeable coating layer impermeable to the passage of said agent that surrounds a portion of said drug core;
- c) a suture tab adhered to and extending from said drug delivery device that is used during surgery to adhere said device to the body of a mammalian organism; and
- d) a permeable polymer coating layer, permeable to the passage of said agent that essentially completely covers the impermeable coating layer b) and the uncoated portion of the drug core a) that is not coated with said impermeable coating layer:

wherein the polymer coating layer d) is of a similar polymer material as said suture tab c) and both polymer coating layer and suture tab have been cured at the same time, bonding both together.

This invention is also directed to a method for providing controlled and sustained administration of an agent effective in obtaining a desired local or systemic physiological or pharmacological effect comprising inserting in a desired location in the body of a mammalian organism the sustained release drug delivery device above.

The method of manufacturing a sustained release drug delivery device according to the present invention comprises: